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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,123	10/03/2003	Bernd Klinksiek	Bayer 10261-WCG	2253

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EXAMINER	
MAEWALL, SNIGDHA	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
01/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/679,123	KLINKSIEK ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *1-15 and 37-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-36 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Applicant is reminded that the office has not received IDS as of this date. This application claims foreign priority under 35 USC 119 over German Application No. 10248619.0 filed on October 18, 2002.

Restriction/Election

Applicant's election of Group II and V with traverse is acknowledged. Applicants Arguments stating that group II and V are drawn to process for producing pulverulent active substance is persuasive, accordingly **Group II (claims 16-36) and V (claim 40)** will be prosecuted in this application.

Claims 1-15 and 37-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected claims there being no allowable generic or linking claim.

Applicant's arguments that searching groups I through V is not burdensome is not persuasive. The inventions presented in groups I to V are in various classes and sub-classes and are distinct. Art anticipating or rendering obvious one group will not necessarily render other groups obvious. Examiner has shown one way distinctness between the groups I-V.

The restriction requirement is still deemed proper and is final.

Claims prosecuted in this application are from 16-36 and 40.

Objections

2. The Specification does not recite the foreign priority in the first line of the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 16-36 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 16 and 40 recite the limitation 'dispersant and additives" and claim 40 recites the limitation "coating material" and "additives". The claims do not specify the specific components, in the absence of which the structural and functional relationship cannot be established. Recitation of specific component is requested.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 16 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16 and 40 recite the limitation "optionally" which makes the claim indefinite. It is not clear whether the limitation is really the limitation. Appropriate correction is required.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 16-36 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over US over Westesen et al. ((US Patent No. 5,885,486) in view of Timothy et al. (Biotechnol. Prog. 200, 16, 402-407).

Westesen et al. discloses an invention relating to the area of administration forms and delivery systems for drugs, vaccines and other bioactive agents. The reference also describes the process of preparing micron and submicron particles of bioactive agents. The process as depicted describes that a solid lipid or bioactive agent or a mixture of solid lipids is melted, stabilizers are added either to the lipid or bioactive agent and to the aqueous phase only depending on their physicochemical characteristics. Stabilizers may also be added or exchanged after homogenization. Drugs or bioactive agents can be melted together with lipid. The aqueous phase is heated to the temperature of the melt before mixing and may contain for example, stabilizers, isotonicity agents, buffering substances, and /or preservatives. The molten compounds are emulsified in an aqueous phase by high pressure homogenization (abstract, column 11 and steps 1-8). Drugs or bioactive agents particularly suitable are listed in column 10, lines 30-60). Ibuprofen and vitamins are also enlisted on the same column. Further in step 8 in column 11, lines 50-55, it is disclosed that the dispersion medium can be reduced by standard techniques such as freeze drying and the lyophilized powder can also be processed into other pharmaceutical formulations such as tablets etc. The bioactive drugs can be dissolved or crystalline or amorphous or a mixture of these crystallographic states. Role of surfactant is described in example 19 on column 24. Various isotonicity agents such as glycerol or xylitol and sucrose, glucose are disclosed on column 10, lines 10-15. The suspensions and lyophilizates can be used for peroral, buccal, pulmonary etc. depending o n the particle size (see column 14, lines 40-45). The reference further teaches the importance of smaller particle size during drug

delivery process (see column 2, lines 10-25). The reference teaches that the drug carrier systems in the micrometer size range are represented as microspheres which are encapsulated (column 3, lines 30-35).

Wetesen et al. do not disclose adding compressible fluid in the supercritical state under pressure to the suspension.

Timothy et al. teaches a method for particle size reduction based on rapid expansion from supercritical fluids, especially CO2. Timothy et al. teaches that the pharmacokinetic properties of both oral and injectable formulations are dependent on the particle size. Small particles are often needed in order to maximize surface are, improve bioavailability and for dissolution requirements. Use of surfactant such as tween 80 is described on page 403 for aiding in the stabilization of drug particles.) also see page 405, second paragraph). Micronization of various drugs were assessed at various temperatures and pressures as depicted on page 404 under the heading "results and discussion." Timothy et al. further disclose that the goal was to produce aqueous suspensions of water insoluble drugs by the RESAS of CO2 solutions(page 402, last paragraph).

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to utilize the compressible fluid in the supercritical state under pressure supercritical fluid such as CO2 as disclosed by Timothy et al. into the process disclosed by Wetesen et al. because Weseten et al. also teaches the preparation of micron and submicron particles consisting of poorly water soluble bioactive agents and their use in drug delivery systems. On e skilled in the art would have been motivated to

prepare pulverulent active substances by utilizing the process of both Wetesen et al. and Timothy et al. with a reasonable expectation of success.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Snigdha Maewall

Art Unit 1615

Gollamudi S. Kishore, PhD
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Group 1600